OPTO-THERMAL MATERIAL MODIFICATION

CROSS REFERENCES TO RELATED APPLICATIONS

This patent application claims the benefit of the filing date of United States Provisional Patent Application Serial No. 60/203,647, filed on May 12, 2000 and entitled Application Technologies, United States Provisional Patent Application Serial No. 60/215,657 filed on July 1, 2000 and entitled Method and Apparatus for Tissue Treatment and Modification; United States Provisional Patent Application Serial No. 60/237,548 filed on September 30, 2000 and entitled Method and Device for Material Conditioning-ISM; United States Provisional Patent Application Serial No. 60/272,653 filed on February 28, 2001 and entitled Method and a Device for Medicated Material Modification and Condition - ISM-IH.

BACKGROUND OF THE INVENTION

Recent studies of human tissue healing processes have demonstrated that an injury to the upper layers of skin will result in collagen regeneration and the growth of a more elastic, younger looking skin.

Several methods for generating this effect have been attempted. A mild photo-damage will cause some blistering followed by natural removal of a few outer layers of the skin. Such a process usually results in a younger looking skin. Similar results can be obtained from a mechanical or opto-mechanical removal of a few surface layers by an abrasive or ablative process, for example. One such process is known as micro-dermabarasion and involves the removal of skin by a stream of Aluminum oxide particles aimed at the surface of the skin. Alternatively, a mechanical scraping of the skin outer surface layers with an abrasive material such as fine sand paper is also used. A more

sophisticated but expensive method involves Er:YAG laser sources of relatively short pulse duration (for example, a few hundreds microseconds long) and a highly water-absorbed wavelength of 2.94 micrometer (or, alternatively 2.79 micrometer of the Er:YSGG free-running lasers). Other methods involve somewhat longer exposure to somewhat more deeply water-penetrating beams such as those of the 9.6 micrometer and 10.64 micrometer CO_2 laser to generate a layer of thermally damaged surface a few hundred micrometers thick. Such deeper skin tissue coagulation usually results in the most aggressive tissue damage and the longest healing time but also in the most effective removal of wrinkles and most effective "skin rejuvenation" and younger-appearing skin.

These prior art procedures represent some beneficial results but also provide potential risk to the patients in the form of excessive damage to the skin, and even of scarring. Abrasive processes often result in excessive cutting, bleeding and pain and sometimes lead to infection, and scarring. Laser treatments are expensive and often result in significant pain, excessive thermal tissue damage and lead to permanent scarring.

SUMMARY OF THE INVENTION

The present invention provides a method and apparatus for the removal and modification of the human skin and underlying tissue layers.

A substance which absorbs electromagnetic radiation in at least a portion of the incident beam electromagnetic spectrum is applied to the surface of a target material. The target material is exposed to electromagnetic radiation, which includes the portion of the spectrum that is absorbed by the substance applied to the surface. At least some of the absorbed energy of the electromagnetic radiation source is absorbed by the substance and is converted to thermal energy at the surface of the target material. The thermal energy thus generated is responsible for vaporizing and ablating part of the skin target material and for

irreversibly thermally modifying a portion of the targeted material. A preferred embodiment envisions the use of carbon-based pigments in suspension within a host material and a continuous emitting electromagnetic radiation source.

The device described in this invention allows for safe and easy-to-use applications of the high absorbing material to the skin surface for the purpose of converting optical energy into thermal energy to effect a change in the targeted skin material by the thermal energy.

BRIEF DESCRIPTION OF THE DRAWINGS

The many attendant advantages of this invention will be readily appreciated by referring to the detailed description in conjunction with the drawings wherein like reference numerals designate like parts throughout the figures thereof, which illustrate preferred embodiments, and wherein:

FIG. 1 is an illustrative cross-sectional representation of human skin with a substance of high absorption applied in the form of a cream or lotion.

FIG. 2 is an illustrative cross-sectional representation of human skin with a thin film containing a substance of high absorption, attached to the skin.

FIG. 3 is a schematic representation of apparatus for the application of electromagnetic radiation and a cooling spray to the skin.

FIG. 4 is a schematic illustration of the two zones of modification on a targeted portion of skin including a zone of ablative material removal and a zone of thermal material modification.

FIG. 5 is a conceptual illustration of the four-parameter regimes that interact together to bring about the desired modification on the targeted area of skin.

FIG. 6 is a graph that illustrates data obtained experimentally relating to tissue modification depth as a function of a source's power and other relevant parameters.

FIG. 7 is a graph that illustrates the effect of the density of particles in a high absorbing substance on the amount of energy coupled to a targeted skin surface.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preferred embodiment of the present invention can be described by reference to Figure 1. Figure 1 shows an illustrative cross section of a targeted area of tissue such as the human skin. A layer of high absorbing substance 10 is placed on top of the epidermis 20 of human skin, which in turn overlies the dermis 30 and fat layers 40. The layer of high absorbing substance 20 is contained within a lotion or liquid for application to the target area. Although this method may be harder to apply and can accidentally contaminate areas of the targeted skin, the high absorbing substance is at least partly in direct contact with the targeted skin area, thus leading to the most efficient transfer of optically absorbed thermal energy to the skin tissue.

Figure 2 shows an alternate preferred embodiment of the invention. A layer of high absorbing substance 100 in the form of a thin film containing particles of the high absorbing substance is placed on top of the epidermis 20. The thin layer of high absorbing substance is contained within a lotion or liquid, for application to the target area material. This method has the advantage of bringing the substance of high absorption in the thin film in more direct contact with the targeted skin area.

Figure 3 shows, a light source 110 emitting energy 120 towards the high absorbing substance 10 on the skin. The high absorbing substance 10 is capable of absorbing at least some of the energy 120. The energy is subsequently thermally conducted towards the deeper portion of the epidermis 20, the dermis 30 and the deeper fat layer 40.

Figure 4 shows that when sufficient energy is deposited in the skin tissue, an ablative zone, 300, of removed targeted material, is formed on the epidermis 20. With more

aggressive interaction, a portion of the entire epidermis 20 and even parts of the dermis 30, may be ablatively removed. Further thermal diffusion and deposition of energy will also lead to the formation of a zone of irreversible damage, 320. In this zone, the targeted material has been thermally altered but not physically removed or ablated. In the specific case of human skin, the tissue in the zone 320 will usually be thermally coagulated.

Such thermal coagulation and thermal injury to the skin tissue will lead to collagen regeneration and the appearance of younger looking skin.

The high absorbing substance utilized in the form of a thin layer on the skin may be carbon particles, Indochina green, graphite, black food coloring, china ink, acrylic tattoo inks, black pigments and their equivalents, for example. The use of these materials has been found to result in an efficient conversion of the electromagnetic energy from the source 110 to thermal energy.

Figure 5 illustrates that the conversion efficiency, i.e. how much of the incident energy has been converted to thermal energy, depends strongly on the interaction between four factors: The energy source parameters (P_L) 500, the energy manipulating components parameters ($P_{O/S}$) 510, the energy removing parameters (P_{er}) 520 and the high absorbing substance parameters (P_{has}) 530. The present invention contemplates four interacting parameter regimes that yield to the final target modification effect.

The first parameter group to be considered, is the source parameter 500. These include the source energy, the source power, the pulse duration (if pulsed), pulse repetition rate (if pulsed), and the source wavelength, if the energy is radiated.

The second group of parameters 510 is the optical /scanning parameters. These define the beam spot size and the motion of the energy along the intermediate material.

The third group 520 is intermediate material parameters. These define the rate of conversion of energy from the source energy to the type of energy that interacts with the target. The fourth group of parameters 530 is the energy removal parameters. These define when, how and the temporal nature of the energy removal from the intermediate material and target material, or both. The interaction of these parameters is illustrated schematically in figure 5.

The interaction between these four parameters, illustrated symbolically in figure 5 by the circle 540, will determine how much of the source's energy is converted to thermal energy.

For example, a test was conducted using a 1 W source scanning a 1 cm^2 area at a rate of about 6 seconds. Assuming that all the energy is absorbed by the layer of high absorbing substance, 6 Joule is deposited over the 1 cm^2 area.

Assume that the energy absorbed E is thermally conducted to the underlying target area. In the case of human skin, for example, water molecules dominate the underlying tissue cells. Simplifying our analysis by assuming as a first approximation a tissue model which is similar to an equivalent volume of water, we can estimate the amount of energy it would require to coagulate (i.e. bring the tissue temperature to above the temperature of thermal denaturation of approximately 60° C) a volume of tissue (100 μm * 1 cm^2) approximated as a volume of water.

We can use the relationship

$$E = C \, \Delta T \tag{1}$$

Where E is the energy required and ΔT is the increase in temperature.

To take water from 20 degree C to 60 degree C and with the specific heat of water given by approximately Cs=1 cal/g* C°

We get from the relation above E ~ 1.6J

To vaporize this amount of tissue would require bringing the tissue or in our simplified thermal model – the water volume of 1 cm^2 100 μm thick to boiling temperature, and then, further vaporizing that volume. From the relationship of Equation 1 above, the temperature rise of 80°C, would require about 3.2 J.

The heat of vaporization of water at 100°C and 1 atmosphere pressure is 539.6 Cal/gm.

Thus to vaporize the 100 μm thick volume discussed above will require about 21.6J, clearly much more than the total incident source energy in our experiment, about 6J. On the other hand, a 10 mm thick layer of tissue (approximated as water) will require only approximately 0.32 J to raise its temperature from 20°C to 100°C, and 2.16 J to vaporize. What the above calculations show is that to raise an additional volume of 00 μm x 1 cm^2 to 60°C coagulation temperature is about 1.6 J. We see that with a total of about 2.16 J + 0.32 J + 1.68 J = 4.16 J we can vaporize about 10 μm of tissue and coagulate an additional 100 μm thick layer.

This simplified analysis agrees with the order of magnitude of our experiments as illustrated in figure 6. The experimental results of figure 6 show the depth of tissue ablated 620 and thermally damaged 630 in pig skin tissue. The figure shows ablation and thermal damage depth on the tissue depth dimension axis 610, as a function of laser diode fluence, 600 (power = 1 W, scan rate is 1 cm^2/sec, and wavelength = 810 nm absorbed by a high absorbing substance composed of carbon suspension).

We can clearly see that both the depth of ablation and depth of tissue thermal damage are on the order of magnitude predicted by the above analysis.

From the above analysis we can conclude that coupling of X Joules of energy with temporal T(t) and spatially R(r) of energy will lead to the ablation of a layer of thinness Xabl

and leave behind a layer of thickness Xtd of thermally modified tissue. The present invention contemplates four parameter groups responsible for a given energy distribution

$$E(t,r) = F\ [T(t)(r)]$$

The four parameter groups are illustrated schematically in Figure 5. These include the laser parameters, 500, the beam-modifier parameters (including the optical beam modification apparatus and scanning parameters) 510, the energy removal parameters, 520 and the high absorbing substance parameters, 530.

The example above shows that a given parameter combination with 1 W of 810 nm radiation, allows, for example, the generation of 10 μm deep ablation zone and a subsequent thermal modification zone of approximately 100 μm deep. Such an exemplary combination generated 6 J of energy, of which, according to the above analysis, about 4.2 J was needed to generated the effect. If we define this energy as Eth, or threshold energy for interaction, which when applied in conjunction with the parameter combination 540 of figure 5, will result in Zabl=10 μm and Ztd = 100 μm.

Considering the high absorption parameter P_{has} 530, if a single layer of absorbing particles is used, the surface density of the absorber will correspond to the amount of energy coupled to the substance of high absorption and the total amount of incident energy converted into thermal energy.

For the incident power parameters of 1W, 810 nm, with scan rate of $1cm^2$ per six seconds, described above, a single layer Phas with particle density such that only, for example, 1/3 of the target area is covered, will not provide sufficient energy to achieve the effect of vaporizing 10 μm of tissue and thermally modifying 100 μm. While thermal diffusion will provide thermal effect even through the gaps in the surface coverage (for example, if a heat-removing substance is applied every 250 ms, heat diffusion of about 500

μm within this time, would essentially assure complete energy coverage of the target surface) the total amount of energy deposited in the tissue will be 2/3 less then in a uniformly covered surface as the portion of the beam that does not encounter Phas particles, continues to propagate through the skin unimpeded.

On the other hand, if E > Eth, then one can compensate for the high absorbing substance, Phas lower particle density, with a higher source power.

For example, if in the experiment discussed above we employ a power source of, for example, 3 W, the sources now deliver 18J in 6 seconds. While 1/3 of the particles will couple approximately 1/3 of the energy, the same total quantity of energy will be coupled to the targeted area. Heat diffusion will then assure that this same overall quantity of coupled energy will be distributed to the entire area.

With a spot size of, for example, about 200 μm and a dwell time of about 10 ms, even small, roughly single micron size particles, will allow heat diffusion to roughly the same area on the same time scale. Thus a uniform Phas particle coat with a 1W beam dwell time of about 10 ms will cover about the same area with thermal energy as a coat with 1/3 the particle density but with 3 W power.

The above discussion thus demonstrates that the parameters combination 540 of Figure 6, allow compensation of sources power by varying the high absorbing substance concentration and vice versa.

The thickness of the high absorbing substance is another component of the parameter group 530 of Figure 5 that plays an important part in determining the target (or tissue) effects. If the absorbing particles are poor thermal conductors, depositing multiple layers of absorber on top of the target will result in significant source energy being absorbed in the upper layers with little getting to the lower layers before the heat remover is applied. On the other hand,

applying high absorbing particles in suspension in a substance with improved thermal conductivity will assure that the applied energy is conducted to the target material. One can then allow gradual thermal energy application to the target as sequential scan passes are stacked and add their thermal energy to the tissue. The present invention contemplates ablatively removing a portion of the high absorbing substance coat with each pass resulting in a self-limiting scheme allowing only a finite number of passes. Thus only a finite amount of energy is deposited in the target material before the high absorbing coat has been completely removed and no more source energy can be coupled to the target.

The energy removal parameter 520 (Figure 5) as applied by energy removal mechanism 200 (Figure 3) also plays a multiple role in controlling the tissue effect. As was pointed out in the discussion above, it effectively ends a heating cycle by removing the heat from the outer surface of a target. For example, if a single line 1cm long and 0.7 mm wide is scanned in, for example, 100 ms, then heat diffuses about 300 μm from the impacted zone. Activation of the heat-removing mechanism (according to the pattern shown, for example, in figure 3) allows control of spatial distribution and synchronized termination of the thermal effect (by effectively removing the heat source from the surface). In fact, the action of the heat removal mechanism 200 goes even further, because by allowing the operator to very rapidly readjust the surface temperature to even below normal ambient temperature, heat can now be forced to flow out of deeper layers in the tissue. The net effect is creating a spatially and temporally controlled thermal pulse that propagates into the tissue from the high absorbing substance in contact with the tissue surface layer and then, upon instruction from the operator, the heat reverses direction and flows out of the tissue material.

An analogy to the behavior of the flow of thermal energy in the tissue material and the time and space dependence of the distribution of thermal energy density (thermal energy per

unit volume) is the behavior of an electric charge density (for example electron density) under the influence of alternating positive and negative electrodes outside a conducting medium. The thermal energy density under the influence of the deposited light energy (effect of 530 in figure 5) and the heat removing parameter, 520 generated by a device 200 (such as freon like spray or other cryogen spray, or controlled air flow, or temporary contact with cold plates or thermoelectric coolers or other such methods to induce transient heat removal), is much like an oscillating or direction-reversing electron cloud movement.

Various combinations of the parameter groups of figure 5 may be used to achieve the objectives of the present invention, as illustrated by the following examples.

Example 1: Optical heating, no high absorbing substance and no heat removal mechanism is being used. Heat transfer amounts substantially to diffusion.

In this case, initial thermal energy distribution mirrors that of the optical deposition. Heating due to optical scattering is maximal just below the surface.

Example 2: Heating with heat removal applied before and or during irradiation, resulting in peak power and thermal energy distribution below the surface.

Example 3: Heating the target surface optically resulting in initial thermal distribution which mirror the initial optical distribution. Heat removal is then applied to the surface resulting in modification of thermal distribution below the surface. Heat also begins to redistribute itself and diffuse upward towards the upper, now cooler surface. Thermal modification thus does not allow enough time for surface to get fully heated and damaged. Thermal distribution below the surface is temporally and spatially modified according to intended operator design.

Example 4: Application of a highly absorbing substances to the target surface prior to external energy deposition. This leads to initial heating confined to the thickness of high

absorbing substance alone. The operator thus has full control over the deposition layer and the initial heating zone.

Example 5: Initial heating with high absorbing substance allowing heat to propagate ahead a predetermined distance. A heat removal mechanism is then applied to the surface quenching the surface heating. The heat then continues to diffuse deeper into the tissue but the thermal energy below the surface also flows back towards the surface where it is used to reheat the surface. The net effect of this process is to limit the effect of the heating, the amount of heat available for tissue modification, the extent of the damaged tissue and the depth location of damaged tissue.

Example 6: The high absorbing substance is applied and subsequently wiped off so it remains substantially mostly in the pores, depressions and troughs of the skin. In these location it absorbs radiation causing localized points of thermal heating spatially distributed on the target surface. Subsequent illumination by the external energy source results in some of the radiation being absorbed by the localized points containing high absorption substance while the rest of the radiation propagates deeper, heating – to a much lower degree – much deeper into the tissue.

The net effect is rapid heating and expansion of the pores combined with heating of lower/deeper regions of the skin to allow expansion of the lower parts which, in turn, expel through the pores, undesired material which may reside in the skin.

Example 7: The example 6, above, followed by the removal of heat. This causes contraction and expansion on the surface (and begins contraction of the target material) while heating deeper regions by optical deposition allows an efficient deeper target expansion.

Example 8: The processes using a high absorbing substance can be modified through a high absorbing substance applicator device to achieve the following effects:

1   Heating of a very thin layer of high absorbing substance. Heat is transferred to the skin.

2   Heating of a "diluted" high absorbing substance suspended in a layer of other material.

3   Wherein other material is an insulator – thereby mitigating the amount of heat transferred but also maintaining heat in that layer for a longer time.

4   Wherein the other material is an insulator – thereby mitigating the amount of heat transferred down to the lower tissue but allowing accumulation of heat in the surface layer allowing material removal through explosive ablation of the applied surface layer.

5   Wherein other material is a conductor– thereby enhancing heat transfer to the tissue.

6   Whereby the above method is followed by surface heat removal.

7   Where the high absorbing substance is also insulating thus resulting in ablation of the surface with substantially mostly mechanical shock to tissue.

8   Wherein the high absorbing substance is partially transmitting resulting in both deeper optical" heating and intense surface heating.

9   Following the heating phase by heat removal resulting in intense heating at below surface but a more delicate spatially larger heating at the surface.

Another way to create a precise effect with a disposable is to create a certain film. For example one can create a uniform suspension of high absorbing substance in a host material such as paraffin, paper, metallic matrix, insulator matrix, thermal insulator or plastic matrix, thermally conducting matrix, jelly, agar or other hosting material. The operator can

then slice it to a precise thickness (for example from a preferred thickness of about 10 micrometer to as much as about a 100 micrometer thick - although many other thicknesses can be contemplated). The process is much like that used in histological slides preparation. A slice with the desired particle size and the desired concentration is prepared and is coated with adhesive to allow it be attached to the targeted area of the skin.

Such a film can be packaged in a sterile package and can come in various sizes and shapes. Such a package can then be opened prior to use, and the operator can cut it with sterile scissors to the desired shape. The film is then attached over the desired targeted area creating a precise special localization of concentration and density and particle size and thickness of layers.

Light traveling through the film containing the high absorbing substance, activates the product in order to cause thermal injury to enter the tissue. The solid film preferably becomes adhesive upon contact with a moist target and adheres to a given location. The adhered film allows high spatial control and eliminates the more messy cream or lotion method of applying a substance of high absorption. The film visually changes in color as the high absorbing substance interacts with the incident energy. Some portions of the film are consumed by the applied light source.

The consumption of the film shows the operator where they have treated, and how long and when the product expired.

With the film or cream of high absorbing substance in place, a site undergoing interaction is visually altered and the handpiece may be used in a free hand motion to cover a larger area. The film will change in appearance, showing the area treated and confirming the product has been consumed. The operator continues to move the handpiece over the target area until the film changes its appearance uniformly to the one indicating proper treatment.

The film may be designed to be thin enough so it does not diminish the effectiveness of thermal energy conduction due to the energy source or heat removing source that are heating or cooling the skin. The film may incorporate anesthetics drugs, nutrients and coolants. The film could have its own cooling mechanism built into it.

Additional alternate structures are contemplated for a device using an energy source which emits radiation which, in turn, is absorbed by a thin layer of intermediate material. One surface of the intermediate layer contains an absorbing substance, which is capable of absorbing the radiation of the energy source inside the handpiece. A second property of the intermediate substance is that it is capable of transmitting absorbed energy from the side facing the energy source to the side in contact with the target material (the material to be modified). A third property of the intermediate material is that all the absorbing substance is contained in a region of the intermediate material, which is accessible to the radiation from the energy source but which is – in a preferred embodiment - not in direct contact with the target material.

Alternatively, the intermediate material contains an absorber that is in contact with the target material. However, intermediate material and the high absorbing substance are made of biocompatible material which can be used in contact with skin without causing an adverse effect. In the more general case, the high absorbing substance and intermediate material can be in contact with the target material if it does not have an adverse effect on the target material. For example, high absorbing material can consist of carbon particles in solution as in Higgins Black Magic ink. A paper matrix can be a 0.05 mm thin paper with the carbon solution capable of adhering to the surface of the paper film.

The composition of the high absorption substance can be adjusted to obtain the desired optimal tissue modification. The matching to optimize the interaction 540 in Figure 5

is accomplished by adjusting the source parameters P_L 500 and Optical/scanner parameters Po/s 510 in figure 5, to that of the high absorption substance parameters, P_{has} 530.

Reference is now made to the settings for the laser or optical scanner.

The fluence F at a given point and time on the target surface is given by,

$F = P / (L_x \, NU_x \, D)$

Where P is the source's power in Watts, Lx is the length of scan in the X-direction (the horizontal direction), NU_x is the scan frequency in the X-direction and D is the spot size diameter.

The actual energy in the tissue is determined by a combination of the effect of the energy absorbed by the high absorbing substance and its conduction coefficient (CC) responsible for transferring the thermal energy to the tissue.

Thus, the thermal energy transferred to the tissue (recall that the fluence is simply the energy per unit area) is proportional to

E tissue $\sim$ (E absorb in cream) * Conduction coefficient

Now if we use an absorber which also acts as an insulator in the medium, the conduction coefficient then becomes a function of the high absorption substance density (ρ).

E abs = $FUN(\rho)$

If we design the high absorbing substance (HAS) as a good insulator, material conduction will in general decrease as a function of HAS density ρ.

With these considerations we have effectively designed a system such that incident energy conversion to thermal energy is increased with the HAS density, but the transfer of this thermal energy from the layer of HAS to the targeted material surface is diminished with increased HAS density. This situation is depicted by Figure 7.

As shown in Figure 7, the absorbed energy 710 increases with HAS density 700, while the transferred thermal energy to the tissue 720 is decreased as a function of HAS particle density. The total amount of energy transferred to the targeted material surface, 730, is thus, a combination of these two effect and is demonstrated in figure 7 by the curve 740. Optimal and maximum thermal energy deposition in the targeted tissue surface corresponds to the location 750 shown in Figure 7. The curve 720 shows the tendency to decrease coupling due to increased HAS particle density and the associated decreased thermal conduction. The curve 710 shows the tendency to increase energy coupling with increased HAS particle density and increased absorption. The curve 740 shows the actual effective energy coupling to the target material surface due to the combined effect of curve 710 and 720.

The correct calculation of the amount of energy deposited in the target material should thus be

$$F_{effective} = P_{effective} / (L\ NU_x\ Diameter)$$

Where $F_{effective}$ is given by

$$P_{effective} = (Incident\ power\ *\ Absorption)$$

To calculate a manipulation of the beam power as a function of HAS particle density we follow the procedure below:

We assume a uniform complete absorption in tissue when $\rho = \rho_{ideal}$

We then assume that when $F = F_{ideal}$ one gets the desired tissue effect

We set the laser or optic scan parameters - Power, Lx, NUx and beam diameter at the target so that to $F \gg F_{ideal}$

So we are certain that thermal damage to the target material will occur.

We then REDUCE ρ to $\rho < \rho_{ideal}$ so that less power is absorbed and the incident fluence is again close to the "ideal" fluence F_{ideal}.

Obviously the dependence of HAS particle density on the laser or optical scanner parameters to achieve a desired tissue or target effect allow a large number of permutations and large number of combinations to be selected.

If a different high absorbing substance (HAS) particle density r is provided and if the high absorbing substance particle density is too low – no effective interaction occurs. On the other hand, if the high absorbing substance particle density is too high – a burn might occur.

If HAS particle and the host substances are maintained at a constant conductance level, the deposited energy density will increase monotonically as a function of the HAS particle density until the surface is completely covered with HAS.

Such a situation in combination with the increasing source power levels will result in increased thermal loading and ultimately burn and blister.

It is preferred that the film is designed to be thin enough so it does not affect the cryogen that is cooling the skin. The film can incorporate anesthetics drugs, nutrients and coolants that could even allow the film to have a cooling mechanism built into it.

One way of creating such a film that adheres to the skin surface is by using a starch paper such as rice paper or potato starch paper. High absorption substance particles according to the correct composition, proportions and design described above may be incorporated into the starch papers or may be added after the paper has been formed. The method allows precise control of the thickness of the film or paper sheet, as well as precise control of the paper composition and HAS particle density, particle size and chemical content. The paper is then being consumed with successive paths so at the end of a pre-

determined number of passes, substantially very little HAS particles are left behind and the

interaction is self-suspended adding to the safety of the device.

An example of a method for preparing a Potato Starch film with high absorbing

particles suspended within it is given below:

> 1.5 cup of water
> 1 spoon of potato starch
>
> Mix starch in cold water first
> Stir thoroughly and make sure all is dissolved
> Place mixture in pot and bring to a boil (1/2 way)
> Mix HAS (Food coloring carbon particles) into liquid
>
> Bring to a boil allowing liquid to rise close to the top of the pot
> (Stir regularly to make sure no clumps form)
>
> Remove / turn off heat and allow to dry on the side of the pot.
> Approximately 15 minutes, depending on thickness.
>
> If it is too thin redo but at lower temperatures.
>
> It is very important that the liquid and starch concentration
> determine how thickly the side of the pots will be coated. The
> process can be repeated a few times to make a thicker coat.

Alternate films may be used. For example, one can create a uniform suspension in a

paraffin, or in a jelly or agar. Then slice it to a precise thickness (e.g. 5 micrometer) much

like in histology slide preparation. A slice with the desired particle size and the desired

concentration is prepared and is coated with adhesive to allow it be attached to the targeted

area of the skin.